

Application No. 10/098,683
Reply dated May 14, 2008
Reply to Office Action of March 14, 2008

REMARKS

In the Office Action, the Examiner rejected claims 54-65, 67-78, and 104-106 (including independent claim 54) under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In doing so, the Examiner indicates that "Applicant failed to disclose a liquid fusion promoting material and a solid fusion promoting material at the time the application was filed (see claims 54, 67, and 104-106)." According to the Examiner, "the terms 'liquid' and 'solid' cover other materials in addition to those disclosed by the applicant," and "although the materials disclosed by the applicant may inherently contain these properties, the applicant did not disclose all liquid and solid fusion promoting materials." In response, Applicant submits that the Examiner has not made a *prima facie* case for the rejection under 35 U.S.C. § 112, first paragraph.

According to MPEP § 2163.III.A, a *prima facie* case under 35 U.S.C. § 112, first paragraph, requires that the Examiner provide "reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed." Applicant notes that MPEP § 2163 II.A.3(b) indicates that "each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure" to comply with the written description requirement of 35 U.S.C. § 112, first paragraph. According to MPEP § 2163 II.A.3(b), citing *Hyatt v. Boone*, 146 F.3d 1348 (Fed. Cir. 1998), "where an explicit limitation in a claim 'is not present in the written description whose benefit is sought it must be shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation.'" Thereafter, MPEP § 2163 II.A.3(b) cites the following precedential example where claims can and cannot derive inherent support from the specification:

To establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient."

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(MPEP § 2163 II.A.3(b), citing *In re Robertson*, 169 F.3d 743 (Fed. Cir. 1999).) As discussed below, Applicant submits that independent claim 54, and dependent claims 67 and 104-106 are supported by the inherent properties of hydroxyapatite, tricalcium phosphate, and bone morphogenetic protein (BMP).

Both hydroxyapatite and tricalcium phosphate are generally used in solid form as fusion promoting materials, and BMP is generally used in liquid form as a fusion promoting material. In fact, in the case of the implant coatings referenced in Applicant's specification, Applicant submits that, as used to promote bone fusion, the solid states of hydroxyapatite and hydroxyapatite tricalcium phosphate, and the liquid state of BMP are inherent, not probable or possible, properties of those materials.

Given the inherent properties of hydroxyapatite, hydroxyapatite tricalcium phosphate, and BMP, Applicant submits that no new matter has been introduced in the claims. Furthermore, because a person of ordinary skill in the art at the time the patent application was filed would have understood that Applicant disclosed solid and liquid fusion promoting materials, Applicant submits that the Examiner has not made a *prima facie* case for the rejection under 35 U.S.C. § 112, first paragraph. Therefore, the Examiner's rejection of claims 54, 67, and 104-106 under 35 U.S.C. § 112, first paragraph, is deemed to be overcome.

Also, the Examiner objected under 35 U.S.C. § 132(a) to amendments to the Abstract included in Applicant's Office Action Response of June 18, 2007. Given that claims 54, 67, and 104-106 are patentable over the Examiner's rejection under 35 U.S.C. § 112, first paragraph, Applicant submits that the Abstract is adequately supported by the original disclosure. Hence, no new matter has been introduced in the amendments to the Abstract, and the Examiner's objection to the Abstract under 35 U.S.C. § 132(a) is now moot.

Additionally, the Examiner rejected claims 54-65, 67-90, and 92-108 (including independent claims 54 and 79) under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,026,373 to Ray et al. ("Ray"). In doing so, the Examiner indicates that "it would have been obvious to one having ordinary skill in the art at the time the

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invention was made to employ the bone growth promoting materials as claimed in Ray's implant in order to promote new bone growth, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice."

In response, note that independent claim 54 recites an apparatus comprising an interbody spinal fusion implant, and a liquid fusion promoting material and a solid fusion promoting material provided in the hollow interior of the implant. Furthermore, note that independent claim 79 recites an apparatus comprising an interbody spinal fusion implant, and a bioactive material and a bioresorbable material provided in the hollow interior of the implant. However, Applicant submits that Ray does not teach or suggest the interbody spinal fusion implant of independent claim 54 with the liquid and solid fusion materials provided in the hollow interior of the implant, or the interbody spinal fusion implant of independent claim 79 with the bioactive and bioresorbable materials provided in the hollow interior of the implant.

Furthermore, besides making an assertion that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the bone growth promoting materials as claimed in Ray's implant in order to promote new bone growth," the Examiner has not pointed to any teaching or suggestion in the prior art affording such an assertion. More specifically, the Examiner has not pointed to any teaching or suggestion in the prior art for liquid and solid fusion materials provided in the hollow interior of the interbody spinal fusion implant and for bioactive and bioresorbable materials provided in the hollow interior of the interbody spinal fusion implant as recited in independent claims 54 and 79, respectively. Accordingly, Applicant submits that independent claims 54 and 79 are not obvious in view of the Examiner's rejection under 35 U.S.C. § 103(a) based on Ray.

In conclusion, Applicant submits that independent claims 54 and 79 are patentable and that dependent claims 55-65, 67-78, 80-90, and 92-108, dependent from one of independent claims 54 and 79, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim. Therefore, in view

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of the foregoing remarks, it is respectfully submitted that the claims, as amended, are patentable. Accordingly, it is requested that the Examiner reconsider the outstanding rejections in view of the preceding comments. Issuance of a timely Notice of Allowance of the claims is earnestly solicited.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-3726.

Respectfully submitted,

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